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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robert A. Scott

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EXAMINER

SPIELER, SHAHRZAD

ART UNIT

PAPER NUMBER

1612

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/721,489	Applicant(s) SCOTT ET AL.	
	Examiner SHAHRZAD SPIELER	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-80 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 72-80 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in prosecution are 72-80.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 72-73, and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6565640 B1 to Bengs, et al. in view of US Patent No. 2876217 to Paschall and US Patent No. 5095054 to Lay et al.

3. Bengs, et al teach a composition based on modified starch (polyhydroxycarboxylic acids) comprising plasticizers that may be used as packaging or casting for food, drink or pharmaceutical products, or the controlled release of substances, or for producing a temporary protective coating (see Abstract). Bengs et al teach starch having sugar alcohols of mono or disaccharides, including sorbitol (see column 1, lines 55-61). Modified starches include oxidized starches and examples of fermentative starches include gum Arabic, and gellan gum (see column 4, lines 5-20). The plasticizers taught by Bengs et al. are commercially available products, including gluconic acid, galacturonic acid, glucaric acid or glucuronic acid (see column 4, lines 63-65) and in the amounts of 2 to 30% by weight of said plasticizer (see claim 2) The invention may be used for thermoplastic mixtures for producing moldings or films (see column 5, lines 50-51).

Art Unit: 1612

4. Bengs et al does not teach the cation as claimed in claim 1 of the instant application, or the sequestering agent. Paschall teaches the preparation of starch ethers containing quaternary ammonium substituents (see column 1, lines 15-16). Paschall teaches a suitable solvent as water (12% moisture, see example 7) and a strongly alkaline catalyst added to the mixture to promote the reaction (see column 2, lines 61-63). The alkaline compounds may include alkali metal hydroxides, alkaline earth oxides and hydroxides, and quaternary ammonium bases. The amount of catalyst in which gives satisfactory results may be from 0.01 to 0.2 mole of catalyst per molar weight of glucose residue (see column 3, lines 8-13). The invention taught by Paschall is applicable to all granular starches, including modified forms, for example, modified starches, with acid or oxidizing agents (see column 3, lines 25-30).

5. Lay, et al teach a thermoplastic polymer composition, comprising a destructured starch (see Abstract). The composition as taught by Lay et al. can be processed for the use of pharmaceutical capsules (see column 47, line 65-68). Examples of plasticizers, as taught by Lay, et al, are sorbitol, xylitol, added in concentrations from about 5% to 5 % based on total weight of all components (see column 47, lines 15-22). Examples of coloring agents include known azo dyes, inorganic pigments, such as the oxides of titanium or iron, may be added in concentrations ranging from about 0.001 to 10% by weight of all the components. Lay, et al, further teaches water component to be about 0.5-5% to 99.5 -95% by weight (see claim 6, column 117).

6. It would have been prima facie obvious, at the time of the invention, for one of ordinary skill in the art to use the teachings of Bengs, et al, Paschall, Lay et al to result in the claimed invention of instant claims 72-73 and 75-80.

Art Unit: 1612

7. One of ordinary skill in the art would be motivated to use the modified (polyhydroxycarboxylic acid) starch as taught by Bengs, et al. for the use of a cost effective, homogenous, physiologically non-hazardous and biodegradable shaped articles, such as capsules and films. Furthermore, one of ordinary skill in the art would have been motivated to use the catalysts described in Paschall to promote the reaction and the useful additives as taught by Lay, et al. such as coloring agents and plasticizers for pharmaceutical capsules.
8. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6565640 B1 to Bengs, et al. in view of US Patent No. 2876217 to Paschall and US Patent No. 5095054 to Lay et al and further in view of US Patent No. 4568560 to Schobel and/or "Natural Toxic Compounds of Foods: Formation and Change During Food Processing and Storage" by J. Davidek alone or together.
9. Neither Bengs et al, Paschall nor Lay et al teach the use of EDTA as a sequestering agent or a metal chelating agent.
10. Schobel, while teaching an encapsulated controlled release agent, for example in the use of a denture cleansing compositions and chewing gums, Schobel and "Natural Toxic Compounds of Foods: Formation and Change During Food Processing and Storage" by J. Davidek teach EDTA as a sequestering agent used to maintain a clear solution (see column 7, lines 13-15) and "free radical scavenging compounds, specifically, EDTA" commonly used in food substances.
11. It would have been prima facie obvious, at the time of the invention, for one of ordinary skill in the art to use the teachings of Bengs, et al, Paschall, Lay et al, and Schobel and Davidek to result in the claimed invention of the instant application.

Art Unit: 1612

12. Finally, one of ordinary skill in the art would have been motivated to use EDTA as a sequestering agent in a modified starch capsule, as Davidek teaches that the metal-chelating EDTA has antioxidant effects to protect against toxic effects of divicine-induced health problems and also neutralize radicals which cause cell damage.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAHRZAD SPIELER whose telephone number is (571)270-1557. The examiner can normally be reached on Weekly 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

Application/Control Number: 10/721,489

Page 6

Art Unit: 1612

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